

Notice of Allowability

Application No.

10/647,816

Examiner

Shirley V. Gembeh

Applicant(s)

REO ET AL.

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 31 October 2005.
2. ☒ The allowed claim(s) is/are 1-23 and 25-31.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800

DETAILED ACTION

The following is an examiner's statement of reasons for allowance: Drug is hard to solubilize and that by using the specified pH unexpectedly improved solubility is obtained (see specification at ¶ 0014).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

The claim interpretation for tolterodine related compounds are limited to those compounds listed in the paragraph bridging pages 3 - 4 of the specification which define the compounds that are tolterodine related compounds.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Examiners Amendment

Claims 1, 4 and 5 have been amended to read as follows;

Claim 1 (amended) A pharmaceutical composition in a form of an orally deliverable liquid, the composition comprising water having in solution therein a pharmaceutically acceptable water-soluble salt of a tolterodine related compound" herein is tolterodine, (R)- N,N-diisopropyl-3-(2-hydroxy-5-methylphenyl)-3-

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phenylpropanamine, its (S)-enantiomer or a racemic mixture thereof; a metabolite thereof that exhibits antimuscarinic activity, including (R)- N,N-diisopropyl-3-(2-hydroxy-s-hydroxymethylphenyl)-3-phenylpropanamle (herein "hydroxytolterodine"), its (S)-enantiomer or a racemic mixture thereof; or a prodrug of tolterodine, hydroxytolterodine, thek (S) enantiomers or racemic mixtures. A preferred such compound is tolterodine at a therapeutically effective concentration in the composition; wherein the composition has a pH of about 2 to about 6 and further comprises a sweetening agent and an antimicrobial agent at a concentration that is antimicrobially effective at the pH of the composition.

Claim 4 (amended) The composition of claim 1 wherein the salt has a solubility in water of at least [about]10 mg/ml.

Claim 5 (amended) The composition of claim 1 wherein the salt has a solubility in water of at least [about] 10 mg/ml.

Authorization for this examiner's amendment was given in a telephone interview with Counselor Goddard on January 23, 2006.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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